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10/810,123

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Howard L. Greene

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BRIAN R. WOODWORTH

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EXAMINER

STIMPert, PHILIP EARL

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,123	Applicant(s) GREENE ET AL.	
	Examiner Philip Stimpert	Art Unit 3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7,9-12,23-25 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,9-12,23-25 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 7, 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. (US 5,586,868) in view of Epstein et al. (US 5,464,392) and Jeon et al. (US 2002/0168278).

3. Regarding claim 1, Lawless et al. teach a medical pump (10) for use with a pumping chamber (22) comprising a pumping element (30b) adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle and a passive outlet valve (49b). Lawless et al. do teach pressure sensors (74, 75), but do not teach a position sensor, processing unit, or memory. Epstein et al. also teach a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198, operatively associated through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29,

ln. 3, also equations 1-2 in col. 31) to determine a calculated stroke volume of the pump for a pump cycle and to adjust a stroke frequency (col. 27, ln. 25) of the pump to compensate for variation between the calculated stroke volume and a desired pump flow rate. One of the primary benefits of the pressure sensing apparatus is the ability to precisely and automatically calculate and control the dispensing of medications to a patient (col. 2, ln. 20-32, also col. 23, ln. 4-11). However, Epstein et al. require knowledge of the states of the valves of the pump, thus in order to obtain the benefits of the control system of Epstein et al. in the pump of Lawless et al., a method for detecting valve states must be used in order to perform the necessary calculations for control of the pump. Jeon et al. teach valves and pumps for microfluidic systems, and in particular teach a method for determining the state of a passive valve (30, method discussed in paragraph 128) including processing pressure data to indicate when a valve has opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of determining the state of a passive valve as taught by Jeon et al. in the pump control and monitoring system of Epstein et al. in order to obtain precise, automatic control and monitoring in the pump of Lawless et al. Further, it would be obvious to directly connect the pressure sensor of Epstein et al. to the pumping element (30b) of Lawless et al. in order to obtain the pressure data required by Jeon et al., and to use position sensors to detect the position of the pumping element (30b) of Lawless et al. as taught by Epstein et al.

4. Regarding claim 2, Lawless et al. disclose multiple pressure sensors (74, 75). However, the control system of Epstein et al. requires only a single pressure sensor,

thus it would be obvious to use only one sensor, in order to simplify the design and reduce the cost of the parts.

5. Regarding claim 7, Epstein et al. teach that the programming code executed by the processor sets a stroke frequency (col. 27, ln. 25) for the desired dosage rate based on a nominal stroke volume ($A \times 100$ or $A \times 88$, col. 31, ln. 12-18) and adjusts the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume (according to equations 1-2 in col. 31).

6. Regarding claim 9, Epstein et al. teach that the programming code executed by the processing unit processes pressure data and position data to determine a calculated pressurization volume from a beginning of the compression stroke to the point when the outlet valve opens, and uses the calculated pressurization volume to determine the calculated stroke volume.

7. Regarding claim 25, Lawless et al. teach a medical pump (10) for use with a cassette (10) having a pumping chamber (22) comprising a pumping element (30b) adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle and a passive outlet valve (49b). As modified particularly by Epstein et al., Lawless is modified to include a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198 in Epstein et al., 30b in Lawless et al., operatively associated in Epstein et al. through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the

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position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to determine a calculated stroke volume of the pump for the pumping cycle and to adjust a stroke frequency (col. 27, ln. 25) of the pump to compensate for variation between the calculated stroke volume and a desired pump flow rate. As further taught by Jeon et al., the programming code executed by the processing unit (48) of Epstein et al. processes pressure data from the pressure sensor (40 or 308) in order to identify when the outlet valve (49b) of Lawless et al. has opened.

8. Claims 10-11, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. in view of Epstein et al. and Jeon et al. as applied to claim 9 above, and further in view of Madsen et al. (US 4,850,805).

9. Regarding claim 10, the previously applied references do not teach the calculation of stroke volume using a ratio of pumping chamber expansion (hereafter, "pumping chamber expansion" will be used interchangeably with "compliance"). The patent to Madsen et al. is directed to a pump control system for a cassette type medical pump. In particular, Madsen et al. address the problem of accurately measuring the flow volumes of this type of pump, (col. 1, ln. 32-43), especially due to compliance errors. Madsen et al. teach the following method for control of an infusion pump: "The pumping pressure peak during pumping and the pressure minimum during filling are detected to determine the portion of a pumping cycle required to make the transition

between these two pressure levels. The difference between the two pressure levels divided by the transition portion of the pumping cycle gives a measure of the compliance of the pump chamber. The ratio of the compliance measure to the total cycle, when multiplied by the nominal chamber volume, gives a measure of unpumped volume, which is subtracted from the nominal volume to give the volume actually pumped during a pump cycle,” (abstract, Madsen et al.). Further, Madsen et al. teach that their “control technique gives particularly precise control at low fluid delivery rates where precision is especially important,” (Madsen et al., col. 2, ln. 10-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the pressure data collected by the pressure sensor of Epstein et al. in the pump of Lawless et al. to calculate the actual volume of fluid pumped, correcting for compliance, in order to more accurately control volumes pumped at low rates. In particular, it would have been obvious to one of ordinary skill in the art to program the processing unit to determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume, determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pump to the compliance at the start of the compression stroke, and determine the calculated stroke volume based on the change in stroke volume.

10. Regarding claim 11, Lawless et al. teach a cassette (10) for defining the pumping chamber (22).

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11. Regarding claim 23, Lawless et al. teach a medical pump (10) for use with a cassette (10) having a pumping chamber (22) comprising a pumping element (30b) adapted to intermittently pressurize the pumping chamber (22) during a pumping cycle and a passive outlet valve (49b). As modified particularly by Epstein et al., Lawless is modified to include a pressure sensor (308), as well as teaching a position sensor (see col. 19, ln. 40-47, col. 20, ln. 21-31) operatively associated with the pumping element (198 in Epstein et al., 30b in Lawless et al., operatively associated in Epstein et al. through pumping piston 272 (also apparently mislabeled 276 in col. 19, ln. 41)) to detect the position of the pumping element (198) throughout the pumping cycle, a processing unit (48) in electronic communication with the pressure sensor (40 or 308) and the position sensor, and a memory (404) coupled to the processor unit containing programming code executed by the processing unit to process pressure data from the pressure sensor (40 or 308) and position data from the position sensor (col. 28, ln. 44 to col. 29, ln. 3, also equations 1-2 in col. 31) to set a stroke frequency (col. 27, ln. 25) for a desired dosage rate based on a nominal stroke volume ($A \cdot 100$ or $A \cdot 88$, col. 31, ln. 12-18), determine a calculated pressurization volume from a beginning of a compression stroke of the pumping cycle to the point when the outlet valve opens (col. 31, relation 1, $A \cdot N2$), and determine a change in pressurization volume by subtracting the calculated pressurization volume from a nominal pressurization volume (col. 31, relation 1). As further taught by Jeon et al., the programming code is executed to identify by a slope change in pressure data (paragraph 124) when an outlet valve (49b) of the pumping chamber of Lawless et al. has opened. As further taught by Madsen et al., the

programming code is executed to determine a change in stroke volume by multiplying the change in pressurization volume by a ratio of pumping chamber compliance at the end of the compression stroke of the pumping cycle to the pumping chamber compliance at the start of the compression stroke of the pumping cycle, determine a calculated stroke volume based on the change in stroke volume, and adjust the stroke frequency to compensate for variation between the calculated stroke volume and the nominal stroke volume.

12. Regarding claim 24, Lawless et al. teach a cassette (10) for defining the pumping chamber.

13. Claims 12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawless et al. in view of Epstein et al., Jeon et al., and Madsen et al. as applied to claim 10 above, and further in view of Holst et al. (US 2003/0055375).

14. Regarding claim 12, the previously combined references do not teach the practice of averaging multiple calculated stroke volumes to produce a single calculated stroke volume. The patent to Holst et al. is directed to a pumping control method for a cassette pump. In particular, Holst et al. teach the acquisition of pressure samples, and that “the plurality of samples are averaged to minimize any pressure sensing variations,” (paragraph 35). As discussed above, the calculated stroke volume is in part dependent upon the pressure data. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a calculated stroke volume comprising multiple calculated stroke volumes averaged together, in order to minimize the effects of pressure sensing variations in the calculations.

15. Regarding claim 31, Madsen et al. teach that the cassette volume (nominal cassette volume) may be empirically determined (col. 8, ln. 24-27). As such, one of ordinary skill would expect measuring error to take place, thus engendering the use of averages (taught above with respect to pressure, but certainly of broader applicability) to minimize the effects of those errors. Therefore it would have been obvious to use an average of multiple nominal pressurization volumes.

Response to Arguments

16. Applicant's arguments, see page 6, filed 28 January 2008, with respect to indefiniteness have been fully considered and are persuasive. The rejections of claims 1, 2, 7, 9-12, and 23-25 under 35 U.S.C. 112 have been withdrawn.

17. Applicant's arguments, see pages 6-8, with respect to the rejection(s) of claim(s) 1, 2, 7, 9, and 25 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Lawless et al. in view of Epstein et al. and Jeon et al. as detailed above.

18. Applicant's arguments with respect to the position sensor of Epstein et al. have been considered, but are not persuasive. In particular, the examiner notes that any digital signal has limits of resolution beyond which further meaningful information cannot be extracted. Further, claim 1, the only claim with language relevant to this argument, recites in significant part only that the position sensor "detect the position of the pumping element throughout the pumping cycle." It appears then, that this limitation is met by the position sensors of Epstein et al.

19. Applicant's remaining arguments with respect to claims 1, 23, and 25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip Stimpert whose telephone number is (571)270-1890. The examiner can normally be reached on Mon-Fri 7:30AM-4:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on (571) 272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Devon C Kramer/
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Examiner, Art Unit 3746
28 April 2008